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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,427	07/19/2001	James Aitken	5017-8122	9777
21888	7590	03/31/2004	EXAMINER	
THOMPSON COBURN, LLP ONE US BANK PLAZA SUITE 3500 ST LOUIS, MO 63101			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,427

Applicant(s)

AITKEN ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-29-02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Drawings

1. New corrected drawings are required in this application because figures 1a-1d, and figures 10a-10b are indecipherable.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.

The abstract of the instant invention contains the term "means". Correction is required.

Information Disclosure Statement

3. The information disclosure statement filed January 29, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copies of the foreign references cited on the IDS have been received. Applicants are requested to supply copies of these foreign references.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3-6, 9, 10, 12, 15, 18 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, 8, 12, 17-21, 25-27 of copending Application No. 09/943,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims differ from those of the '647 application only in that the instant claims are broader than those of the '647 application. For instance, the claims of the instant application recites an actuation member, whereas the claims of the '647 application recite a transport member, however, both members operate in initiating the movement of the test elements to a position where they engage the electrodes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4, 12, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/10558 to Friedlander et al.

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Friedlander et al teach an electrochemical sensor comprising a housing and a plurality of test elements (3) arranged in a stack. The test elements comprise electrodes for determining analytes such as blood glucose, as recited in claims 1 and 15 (page 3, 1st full paragraph). The test elements are arranged inside of a magazine (4). A plate (20), part of the housing, carries corresponding electrical contacts that connect to the electrodes on the test elements. A pusher (35) is used to push the top test element from the stack into a test position. The pusher is actuated by the turning action of screw top (33) via a pusher gear mechanism. This arrangement is equivalent to Applicants' claimed actuation means because it allows the test element to be dispensed upon the rotation of the top (page 5, 3rd full paragraph), as recited in claims 3 and 4. With respect to the sealing means, Friedlander et al teach that the individual test element may be sealed by an O-ring (29). See page 4, 3rd full paragraph. The reference further teaches that the stack of test elements may be sealed by an O-ring (page 5, 3rd full paragraph). With respect to claim 12, Friedlander et al teach that a spring (25) may be used to urge the test elements into test position (page 4, 3rd full paragraph).

Therefore, for the reasons set forth above, Applicants claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Friedlander et al.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2, 5-8, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al in view of US Patent 5,460,778 to Macindoe, Jr.

The disclosure of Friedlander et al is described above. Friedlander et al differ from the instantly claimed invention in that there is no disclosure of foil sealing means, multiple magazines holding stacks of test elements, blade and cutting means for removing the test elements from the magazine, and a processor.

Macindoe teaches an analytical instrument comprising an assay module supply apparatus (17) having a plurality of assay modules, each containing reagents useful in the detection of components of a fluid sample. As shown in figure 10, the assay modules are stacked inside of a plurality of magazines (109). An individual magazine may be removed from the supply apparatus, as recited in claim 16 (col. 8, lines 30-36). With respect to the cutting means, Macindoe teaches that sheets of thin foil are adhered to the front surface of the compartments (119) of the magazine to prevent moisture or debris from entering into the compartment (col. 8, lines 56-63). Macindoe teaches a cutting assembly (171) which tears away a portion of the sheet material from compartments (119), as recited in claims 5-7 (col. 9, lines 42-49). With respect to the processor recited in claim 14, Macindoe teaches a microprocessor

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for controlling the operation of various components (such as temperature and timing) of the instrument.

It would have been obvious to one of ordinary skill in the art to modify Friedlander et al by using multiple magazines holding the test elements. Such would allow more test elements to be stored in a single device in a space effective manner. This would also allow the test elements to be replenished in one magazine without affecting the other test elements.

It would have also been obvious to one of ordinary skill in the art to modify Friedlander et al by using a cutting mechanism to tear away the foil protective layers covering each test element. This would allow each testing element to be separately stored and protected and would further aid in automating the movement of test elements from the magazine.

Further, it would have been obvious to one of ordinary skill in the art to include a processor in the device of Friedlander et al so that the movement of the test elements into a testing position and the analysis of the sample could be automated and thus, alleviating the need for user intervention.

11. Claims 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al in view of US Patent 6,534,017 to Bottwein et al.

The disclosure of Friedlander et al is described above. Friedlander et al differ from the instantly claimed invention in that there is no disclosure of a sliding member and no disclosure of the physical description of the test elements to be used.

Bottwein et al teaches a test element storage device comprising a magazine having stacked test elements disposed therein. With respect to claim 11, Bottwein et al teaches using a slide mechanism that serves to remove test elements. The slide is moved incrementally by a length corresponding to the width of the test element. Bottwein et al teaches that the slide can

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be coupled to a rod, wherein rotation of the rod causes a thrust of the slide and movement of the test elements (col. 6, lines 1-51). It would have been obvious to one of ordinary skill in the art to use a slide mechanism in conjunction with pusher of Friedlander et al to allow the movement of the test elements to be driven by a control unit in an automated manner, where the slide and pusher are both operated by drive units.

With respect to claims 18 and 19, Bottwein et al teaches using testing elements having test zones covered on a portion of the test element. In figure 1B of Bottwein et al, the test elements are shown having test zones (3) on a support (2). The thickness of the test zone (working area) is greater than the thickness of the non-test zones (non-working area). These testing elements are conventionally used in the analytical testing field and it would have been obvious to one of ordinary skill in the art to use such testing elements in the device of Friedlander et al.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al in view of US Patent 4,279,861 to Jessop.

The disclosure of Friedlander et al is described above. Friedlander et al differ from the instantly claimed invention in that there is no disclosure of a ratchet wheel.

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Jessop teaches a cartridge for containing test elements for use in performing biological analyses. In moving the test elements out of the cartridge, Jessop teaches using a ratchet wheel as a means for preventing the test elements from moving backwards into the cartridge (i.e. as an anti-backup means). See col. 5, lines 28-51. It would have been obvious to one of ordinary skill in the art to include a ratchet wheel in the device of Friedlander et al to prevent the test elements from accidentally being moved backwards into the magazines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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